

REMARKS

Reconsideration of this application, as amended, is respectfully requested.

The specification and claim 16 have been amended to overcome the objections thereto.

Claims '13, 14, 16, 17, 18, 22, 23 and 24 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Gautier. Claims 15 and 19-21 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Gautier. Applicants respectfully submit that the claims, as amended, are not anticipated or rendered obvious by Gautier, since Gautier ascribes no preference to the shape of the stud.

The formation of the stud in cross-section as N-fold with $n = 2, 4, 5$ or 6 (an n -sided body), or as a polygon or an oval, has the advantage that the resistance to rotation is substantially improved. Rotation of the slide shell 1 in the plastic jacket 2 is possible only with a relatively great displacement of plastic in the embodiment of pin 3 (page 5, line 12-13). Applicants have shown that the shape or configuration of the stud, i.e., the shape of its cross-section, has a significant effect, i.e., improved resistance to rotation. Gautier does not address this, nor does Gautier teach or suggest the advantages of providing a stud shaped in the manner claimed. A *prima facie* case of obviousness has, therefor, not been established.

Since the evidence that the Examiner purports to be lacking is actually provided in the specification, and in view of the discussion above, allowance is respectfully requested.

Any fees due that are not provided herewith may be charged to deposit account no. 50-0624.

Respectfully submitted,

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Ceramic sandwich insert for an artificial hip joint
FIELD OF THE INVENTION

The invention relates to a sandwich insert having an inner ceramic sliding cup, which is surrounded by a plastics cover, for insertion into an outer metal shell of an artificial hip joint.

BACKGROUND OF THE INVENTION

An artificial hip joint as a rule consists of a sliding cup which is inserted into an outer metal shell either directly or by way of a plastics cover. This metal shell is implanted in the pelvic bone. The combination of sliding cup and plastics cover is termed a sandwich insert.

15 A shaft, on which there is arranged a ball head that articulates in the sliding shell, is implanted in the femur.

20 In the case of artificial hip joints it is possible that the ball-head shaft will strike against the acetabulum time and time again. If the impact forces are sufficiently great, this can result in the mechanical acetabulum-composite breaking up. In particular, sandwich socket systems are at risk here, since the polyethylene (PE) that is predominantly used can only put up insufficient resistance against these forces of impact.

25 Sandwich inserts are produced in various ways.

30 In one system, the ceramic sliding cup or the insert respectively has plastics material injection-moulded around it, with recesses being arranged on the sliding shell. What is disadvantageous about this is the fact that the polyethylene (PE)-properties that result when the same is heated are inferior. Furthermore, there is

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5 a thermal shock for the ceramic sliding cup. In addition to the outlay on injection-moulding on account of the injecting mould and the handling of the hot portions, the large amount of construction space that is required is disadvantageous.

10 In the case of an alternative system, the sliding shell is anchored by a conical clamp in the plastics cover, with there being to some extent, instances of low resistance of the composite component. The disadvantage here as well is the large amount of construction space that is required.

15 The process of pressing the sliding cup into the plastics cover in the warm state is also preferably employed. In this connection, however, there occur to some extent instances of composite component strength that are too low. Moreover, narrow tolerances must be observed on account of the press-connection.

20 **OBJECT AND SUMMARY OF THE INVENTION**

The underlying object of the invention is to improve a sandwich insert [in accordance with the preamble of claim 1] in such a way that a high level of resistance to sudden change is achieved with a small amount of construction space being required.

25 In accordance with the invention this object is achieved by the sliding cup having a stud at its outer end that is remote from the opening, whereby the resistance to sudden change is substantially increased, with a small amount of construction space being required, since the stud necessitates almost no increase in construction space.

30 35 Advantageously, the stud is arranged on the central axis or the axis of rotation of the sliding cup and has

an axial length of 1. - 8 mm, preferably approximately 2 mm. This length suffices in order to increase the resistance to sudden change. However, other lengths can also be used.

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In a preferred embodiment, the stud is arranged in the plastics cover by means of a fit. This can be an interference fit, a transition fit or a close clearance fit, depending on the desired resistance-configuration.

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The stud can project completely through the plastics cover, project into it or else be surrounded at least in part by the plastics cover. It is preferably even completely surrounded by the plastics cover.

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The cross section of the stud forms an n-sided body with $n = 2, 4, 5$ or 6 . Alternatively, the cross section of the stud can even form a polygon or be oval.

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The sliding shell is preferably of a spherical or a stepped structural form on its outside. Spherical structural forms require a very small amount of construction space.

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In an advantageous embodiment, the plastics cover embraces the sliding shell at its open end.

The sandwich insert is preferably produced by pressing the sliding shell into the plastics cover.

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Further features of the invention follow from the figures which are described in the following and in which] BELow.

BRIEF DESCRIPTION OF THE FIGURES

35 Figure 1 shows a sandwich insert in accordance with the invention in a spherical structural form;

Figure 2 shows a sandwich insert in accordance with the invention in a stepped structural form; and

5 Figure 3 shows advantageous configurations of the cross sections of the stud.

DETAILED DESCRIPTION

Figure 1 shows a sandwich insert having a sliding cup 1 of spherical structural form. During production, this 10 sliding shell 1 is pressed into the plastics cover 2. The plastics cover 2 preferably consists of polyethylene (PE). The upper edge of the sliding shell is constructed so as to be flush with the upper edge of the plastics cover 2. In order to increase the 15 resistance to sudden change, that is, also to anchor the sliding cup 1 in the plastics cover 2 in a better way, a stud 3 is arranged at the end of the sliding shell that is remote from the opening on the axis of rotation or central axis 4. This stud 3 projects into 20 the plastics cover 2 in this embodiment.

Figure 2 shows an alternative embodiment with a stepped structural form for the sliding cup 1 on the outside thereof. Here, as well, a stud 3 is arranged on the 25 central axis 4 and is completely surrounded here by the plastics cover 2. The axial length of the stud 3 is then approximately 2 mm.

In view of the fact that the sliding shell 1 is pressed 30 into the plastics cover 2 during production, the stud 3 is inserted in the plastics cover 2 by means of a fit.

At its open end the plastics cover 2 embraces the 35 sliding cup 1, thereby improving the securement. The collar 5 of the plastics cover 2 that rests on the upper side of the sliding cup 1 covers almost half of

IT IS CLAIMED [Claims]

1. Sandwich insert having an inner ceramic sliding cup (1), which is surrounded by a plastics cover (2), for insertion into an outer metal shell of an artificial hip joint, characterized in that the sliding cup (1) has a stud (3) at its outer end that is remote from the opening.
- 10 2. Sandwich insert according to claim 1, characterized in that the stud (3) is arranged on the central axis (4) of the sliding cup (1).
- 15 3. Sandwich insert according to claim 1 or 2, characterized in that the stud (3) has an axial length of 1 - 8 mm, preferably approximately 2 mm.
- 20 4. Sandwich insert according to one of claims 1 to 3, characterized in that the stud (3) is arranged in the plastics cover (2) by means of a fit.
- 25 5. Sandwich insert according to one of claims 1 to 4, characterized in that the stud (3) projects into the plastics cover (2) or projects completely through it.
- 30 6. Sandwich insert according to one of claims 1 to 4, characterized in that the stud (3) is surrounded at least in part by the plastics cover (2).
7. Sandwich insert according to one of claims 1 to 6, characterized in that the cross section of the stud (3) forms an n-sided body, preferably with $n = 2, 4, 5$ or 6.
- 35 8. Sandwich insert according to one of claims 1 to 6,